

### **REMARKS/ARGUMENTS**

Claims 1 and 4-8 remain in this application. Claims 2 and 9-14 are withdrawn. Claims 1, 6 and 7 have been amended. Claims 6 and 7 have been amended to further define the anchoring screw body, the elongated generally cylindrical member and the reaction element. Claim 6 has been amended to agree with antecedent support for the positioning of the slots forming the weakened portion of the reaction element.

In view of the examiner's earlier restriction requirement, applicants retain the right to present claims 2 and 9-14 in a divisional application.

Claim 6 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, the examiner noting an inconsistency between claims 5 and 6. In response to this, claim 6 has been amended to define the slots as being located "between" the tip portion and the body, consistent with its parent claim 5. It is, therefore, believed that the rejection has been obviated.

Claims 7 and 8 stand rejected under 35 U.S.C. 102(b) as anticipated by Carchidi et al. (U.S. 5,899,940). Claim 7 has been amended to define the reaction element, among other things, as having a mesh fixation base plate having a plurality of holes formed therein. This is clearly not shown or remotely suggested by the '940 patent and therefore it is submitted that this rejection should be withdrawn.

Claims 1 and 5-8 stand rejected under 35 U.S.C. 102(e) as anticipated by Schumacher et al. (U.S. 6,325,803). The examiner noted that the reference discloses an anchoring screw body 32 having internal and external threads along with an elongated cylindrical member 30 having a head 34. The examiner stated that head 34 includes a driving surface and noted that reaction surface 110 has a flat surface portion with a relatively wide mesh body having a plurality of holes and a solid tip portion also having a flat surface portion and noted that the driving surface may be driven by a hammer, for

example, and that the solid tip portion may comprise any one of the solid corners of element 110. The examiner read the larger holes in element 110 as creating a weakened portion. The examiner concluded that the Schumacher et al. device meets the structural limitations of the claims and is inherently capable of being used as a maxillofacial anchoring and distraction system.

It is respectfully submitted that the claims, particularly as amended, patentably distinguish over the Schumacher et al. patent for the following reasons.

The Schumann et al. patent relates to a device for securing an elongated locking plate to the mandible with fasteners, each having a removable head portion, by engaging the bone threads of the lower portion of the fasteners with the mandible and threadingly engaging the head portions with the locking plate, unthreading the head portions from the main body of the fasteners to allow removal of the locking plate without removing the fasteners from the mandible, performing a surgical procedure, such as the removal of a cancerous growth, and then re-securing the locking plate to the fasteners with the removable head portions. There is no suggestion of using the device for maxillofacial alveolar and small craniofacial skeletal distraction. Further, a number of structural limitations of the claims, particularly as amended, are not shown in the reference. For example, the anchoring screw body for which the examiner relies on head member 32 of the reference. Independent claims 1 and 7, as amended, call for an anchoring screw body having an external bone thread. Head 32, on the other hand, has external threads for reception in metal locking plate 14. There is no suggestion of providing head member 32 of the reference with bone screw threads to enable it to be threaded into a bore in a bone.

Independent claims 1 and 7 also call for an elongated generally cylindrical member having an external threaded portion for threaded engagement in the threaded bore of the anchoring screw body, the generally cylindrical member being capable of being inserted in the bore of the anchoring screw body with the distal end inserted from the upper side of the anchoring screw body, the elongated generally cylindrical member having the distal end extending out of the threaded bore beyond the lower side of the

anchoring screw body and being formed with a distraction force transferring surface and, as defined in claim 1, the generally cylindrical member being removable through the upper side upon completion of distraction. The examiner relies on main body 30 of fastener 18 for the claimed structure, however, the distal end (bone threaded lower end 36) is not capable of being inserted in the threaded bore of head member 32 from the upper surface and is totally different from the claimed structure.

Claim 1 further calls for the reaction element to have a relatively wide mesh body and a narrow, relative to the mesh body, solid tip portion extending from the body. This is not shown or suggested by the reference.

Independent claims 1 and 7 also call for a reaction element having a flat surface portion for engagement with the distraction force transferring surface of the generally cylindrical member. The examiner relies on reinforcing member 110 of the reference for this and notes that any one of the solid corners of member 110 can read on the solid tip portion. However, both independent claims 1 and 7 call for the flat surface of the reaction element for placement in a horizontally extending osteotomy in a bone, The structure of reinforcing member 110 shown in the patent clearly is not appropriate for such positioning.

Thus the '803 device does not meet the structural limitations of the claims nor is it inherently capable of being used in a way in which applicants' system is used without completely changing the structure shown in the patent.

With respect to dependent claims 5, 6 and 8, since they are dependent ultimately on either claim 1 or claim 7, they should be allowable with their parent claims. In addition, it should be noted that the reference does not show a reaction element having opposing slots between a solid tip and a mesh body forming a weakened portion. For the above reasons, it is submitted that claims 1 and 5-8 are neither shown by Schumacher et al. in the 35 U.S.C. 103 sense or suggested in the 35 U.S.C. sense and that the rejection should be withdrawn.

Claim 4 stands rejected under 35 U.S.C. as being unpatentable over U.S. Patent No. 6,325,803 to Schumacher et al. in view of U.S. Patent No. 5,709,803 to Talos et al. Since claim 4 is dependent on claim 1 it should be allowable therewith for the reasons state above.

Pursuant to Section 713.04 of the MPEP, and in furtherance of the PTOL-413 Form provided by the examiner, a telephonic interview was initiated by the examiner on 9 August 2004 in which he identified Patent No. 6,325,803 to Schumacher et al. and indicated that claim 7, in his opinion, did not patentably distinguish over the patent. In response, a proposed amended claim 7 was faxed on 10 August 2004 to the PTO in which further details of the reaction element 17 were added to the claim. This did not place the claim in condition for allowance and was not entered. The next action taken was the issuance of the 27 August 2004 Office Action directed to claims 1 and 4-8.

In view of the above remarks, reconsideration and allowance of the application is respectfully requested.

Respectfully submitted,



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